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A Look at State-Level Risk Assessment in the United States: Making Decisions in the Absence of Federal Risk Values

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State environmental agencies in the United States are charged with making risk management decisions that protect public health and the environment while managing limited technical, financial, and human resources. Meanwhile, the federal risk assessment community that provides risk assessment guidance to state agencies is challenged by the rapid growth of the global chemical inventory. When chemical toxicity profiles are unavailable on the U.S. Environmental Protection Agency's Integrated Risk Information System or other federal resources, each state agency must act independently to identify and select appropriate chemical risk values for application in human health risk assessment. This practice can lead to broad interstate variation in the toxicity values selected for any one chemical. Within this context, this article describes the decision-making process and resources used by the federal government and individual U.S. states. The risk management of trichloroethylene (TCE) in the United States is presented as a case study to demonstrate the need for a collaborative approach among U.S. states toward identification and selection of chemical risk values while awaiting federal risk values to be set. The regulatory experience with TCE is contrasted with collaborative risk science models, such as the European Union's efforts in risk assessment harmonization. Finally, we introduce State Environmental Agency Risk Collaboration for Harmonization, a free online interactive tool designed to help to create a collaborative network among state agencies to provide a vehicle for efficiently sharing information and resources, and for the advancement of harmonization in risk values used among U.S. states when federal guidance is unavailable.

KEY WORDS: Chemical; collaboration; database; harmonization; state

1. INTRODUCTION

U.S. Federal and state environmental agencies are currently at a breaking point. The General Accounting Office estimates that 80,000–100,000 chemicals are currently in use and approximately 700 new chemicals are introduced into commerce each year.(1) As a result, the rate of chemical use and production has surpassed the federal scientific community's ability to provide timely detailed guidance for quantitative risk assessment in the form of safe dose estimates (e.g., reference doses) and cancer risk values (e.g., slope factors).(2,3) These risk values are an essential tool used by state environmental agencies in conducting health risk assessments associated with chemicals in the environment, such as in addressing air and water contamination, hazardous waste site remediation decisions, and assessing the safety

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of products.[4] This article discusses the role of U.S. Environmental Protection Agency (EPA) in developing federal chemical risk guidance, and explores the approaches employed by states when such federal guidance is unavailable. We then examine the use and effectiveness of collaborative approaches to risk assessment in Europe as a possible model for U.S. interstate cooperation. Finally, in an effort to facilitate additional collaboration among state environmental agencies, we introduce a free online interactive tool designed to help to meet the needs of state agency and community risk assessors. The State Environmental Agency Risk Collaboration for Harmonization (SEARCH) tool is intended to facilitate communication and foster collaboration among state risk assessors, by providing access to shared information and resources among state risk assessors.

2. THE FEDERAL–STATE RELATIONSHIP IN RISK ASSESSMENT

Most contaminated sites and emission permitting systems throughout the United States are regulated and managed by state-level agency programs. In selecting cleanup levels and regulatory values, most states rely upon U.S. EPA Integrated Risk Information System (IRIS) database as their primary source of human health risk values.[5,6] IRIS provides qualitative and quantitative data on the adverse health effects of chemical exposure.[5] It contains oral reference doses (RfDs) and inhalation reference concentrations (RfCs) to estimate noncarcinogenic effects of chemicals, as well as oral slope factors, and inhalation unit risks used to estimate carcinogenic risk. Risk managers use these data to make decisions and set regulatory limits to protect public health.[4]

However, IRIS is currently facing many challenges. After the U.S. Government Accountability Office (GAO) conducted an examination of the federal risk assessment process in 2008, GAO reported that EPA is experiencing a backlog of approximately 70 chemical assessments and estimated that more than 287 IRIS assessments are now outdated.[1] GAO cited numerous reasons for the limited level of productivity, some of which are related to the federal process itself, and others that relate to the limited chemical safety data available to conduct a robust assessment. EPA responded by implementing several reforms to improve the process, such as increasing funding and staffing, and restoring EPA's independence in the process so that risk assessments are no longer delayed due to federal interagency reviews. In 2009, a follow-up report by GAO acknowledged EPA's progress, and focused on additional strategies for strengthening and streamlining the IRIS process.[7] Building on GAO recommendations, EPA halved the number of development steps in the process from 14 to 7, shortened assessment development time to 23 months, and brought the 70 chemicals previously in backlog under review.[8] These reforms to the IRIS program represent significant improvements, and will hopefully help to alleviate the gaps in chemical safety information.

The GAO report made it clear that many of the issues impeding the federal risk assessment process are outside of the control of the IRIS program. For example, GAO reported that congressional action has delayed some chemical assessments until new information is available because of the significant economic impact the assessment would have on constituent industries. Additionally, as the scientific complexity of risk assessments grow, EPA must also follow increasingly complex risk assessment guidelines and often use methods and models that are still in development or are being implemented for the first time. Complexities are further compounded by the required inclusion of a comprehensive quantified uncertainty analysis in each assessment. The process is also hindered by the simple lack of toxicity data. Under the current Toxic Substances Control Act,[9] if human exposure to a chemical is not expected, collection of toxicology data may not be viewed as necessary to ensure public safety.[9] The absence of sufficient toxicity data to develop a quantitative dose–response relationship precludes IRIS evaluation.

3. IRIS AND THE CASE OF TRICHLOROETHYLENE (TCE)

TCE is an industrial solvent and degreaser and is a common contaminant in air, soil, surface, and groundwater, identified in over 1,500 hazardous waste sites regulated under the major environmental U.S. laws, including the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act.[10] The history of the TCE assessment at EPA provides a good illustration to help understand the EPA and IRIS process and the time it can take to develop a human health risk value. TCE is globally known to adversely affect human health; it has been shown to have adverse, noncarcinogenic health effects on multiple target organs, including the nervous system, liver, kidneys, and immune system. In

Table I. Timeline of Events for Trichloroethylene (TCE) Toxicological Profile

1989	EPA withdraws TCE Toxicological Review from IRIS
2001	National Center for Environmental Assessment (NCEA) releases draft TCE health risk assessment
2002	Environmental Protection Agency's (EPA) Science Advisory Board reviews the draft TCE assessment
2006	National Academy of Science (NAS) releases report recommending new TCE data be incorporated and NCEA's assessment be reissued
2009	EPA issues Draft Toxicological Review of TCE
2011	EPA issues Final Toxicological Review of TCE

addition, developmental effects have been reported following TCE exposure.[11] The carcinogenicity of TCE has been assessed by the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP).[12,13] TCE has been classified as "probably" and "reasonably anticipated to be" carcinogenic to humans, respectively, by these two organizations based on their respective classification systems.[14] U.S. EPA's TCE risk assessment has been the subject of much controversy. Not until 2011 did the U.S. EPA reach consensus on the carcinogenicity of TCE, concluding that "TCE is characterized as carcinogenic in humans by all routes of exposure."[8]

EPA's consensus statement was the result of a regulatory process that spanned more than a decade. The timeline for EPA's TCE assessment, as reported by GAO, is shown in Table I.[1]

In 1989, the TCE noncancer and cancer risk values were withdrawn from IRIS for further review. In 2001, EPA's National Center for Environmental Assessment (NCEA) released a draft TCE health risk assessment that proposed a range of noncancer values; however the 2001 draft did not offer guidance on how to apply the proposed range of values. This lack of guidance was noted as a major concern by state agency risk assessors.[15] The 2001 draft assessment also characterized TCE as "highly likely to produce cancer in humans." In 2002, EPA's Scientific Advisory Board (SAB) peer reviewed the draft assessment and concluded that the weight of evidence for TCE carcinogenicity suggested that the appropriate classification for TCE was on the continuum between "highly likely to be carcinogenic to humans" and "known to be carcinogenic to humans."[16] The National Academy of Sciences (NAS) reviewed the TCE assessment in 2006 and concluded that the weight of evidence of TCE carcinogenicity had strengthened since EPA issued its 2001 draft assessment, but did not recommend a cancer classification.[17,18] NAS did recommend that new data be incorporated into the assessment and that the assessment be finalized. In November 2009, EPA issued a revised draft toxicological review of TCE that underwent external review,[19] and issued a final toxicological review in September 2011.

The case of TCE illustrates that U.S. states need to use interim approaches for evaluating and managing risk while they await the results of the extensive IRIS review process that can take years to develop and finalize regulatory values for chemicals of environmental concern. Given the limited extent to which IRIS provides comprehensive coverage of risk values for the universe of chemicals of interest, State risk assessors cannot always rely on this database to fulfill their data needs. As a result, chemicals without easily accessible risk values may not be fully considered by states during the risk assessment process.

4. HOW STATES MAKE DECISIONS WHEN NO FEDERAL GUIDANCE IS AVAILABLE

In the absence of federal guidance on risk values, U.S. states turn to other sources of toxicity and risk information, or they work independently to derive their own risk values. The Interstate Technology and Regulatory Council (ITRC) proposed a hierarchy for selecting human health toxicity values based on the merit of the underlying toxicity data and the quality of peer review.[6] Originally prescribed in Risk Assessment Guidance for Superfund,[20] the tiered hierarchy was revised by ITRC as follows:

- Tier 1—EPA's IRIS values. The chemicals listed in IRIS have undergone peer review and are continuously re-reviewed.
- Tier 2—EPA's Provisional Peer-Reviewed Toxicity Values (PPRTVs). The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center develops PPRTVs on a chemical-specific basis when requested by EPA's Superfund program for use in site-specific risk assessments. PPRTVs are developed in a shorter period of time, and although these assessments undergo external peer review, their development does not include a multiprogram consensus review as is done with the IRIS assessments.
- Tier 3—Other Toxicity Values. This tier includes additional EPA/non-EPA sources of

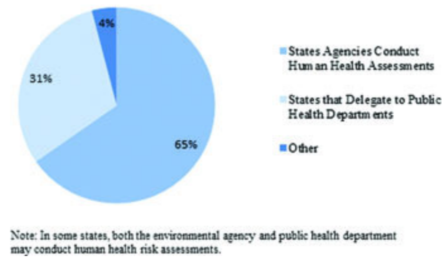

Fig. 1. State agencies with risk assessment capability.

> toxicity information. Priority should be given to sources of information that are most current, peer-reviewed, transparent, and publicly available. Example sources include the California Environmental Protection Agency (Cal EPA) toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels, and Health Effects Assessment Summary Tables (HEAST) values.[6]

While there was general agreement on the use of the ITRC tiered approach, not all states have adopted the ITRC approach, instead opting to establish their own hierarchy. In addition, many states with the technical and financial resources choose to independently derive their own risk values (e.g., California Environmental Protection Agency, Texas Commission on Environmental Quality). Not surprisingly, one of the main factors determining how states handle risk management decisions is the availability of in-house capabilities, which are affected by shrinking state environmental agency budgets. In March 2010, the Environmental Council of the States (ECOS) issued a green report entitled Impacts on Reduction in FY 2010 on State Environmental Agency Budgets. The report summarized data collected from 37 of 50 states that responded to a survey regarding the extent of the financial impact on their environmental programs. ECOS reported that across the country, 2,112 environmental positions have been eliminated or are being held vacant due to budget cuts, and 20 states have reduced or eliminated programs (hazardous waste programs are among those facing reductions).[21] One effect of limited resources is that many states do not have a toxicologist or technically trained staff, which makes it difficult for them to produce their own risk values. Fig. 1 shows the proportion of states with risk assessment capability.

The impact of limited time and resources on risk management decisions is most apparent when states must make decisions regarding chemicals that are not included in IRIS. The variety of approaches can sometimes result in the use of a wide range of toxicity values across the United States. Differences in state-selected risk values, whether due to political or scientific reasons, can lead to questioning of the scientific credibility of the organization or the risk assessment process. Additionally, broad discrepancies between neighboring states can elicit public concern and protest from citizens doubting the degree to which public health is protected.[22] Also, within state agencies there can be political pressure to have risk values no more stringent than neighboring states, driven by the perception that strict environmental regulations can deter new businesses. These issues became apparent when looking at the ways that states chose to regulate TCE in the absence of U.S. EPA risk values.

5. STATES AND THE CASE OF TCE

In the years since 1989 when U.S. EPA withdrew its TCE risk values, U.S. states continued to address ongoing cleanup decisions regarding TCE but did so in disparate ways; the Final Toxicological Review issued by EPA in 2011 will help to standardize the approach moving forward. However, TCE is not unique. Other common contaminants, such as naphthalene, dioxin, and perchloroethylene, have experienced similar delays in the development of an IRIS value, resulting in a wide-variety of state approaches for these chemicals.

To provide insight into how states approached TCE, the Indiana Department of Environmental Management (IDEM) conducted a survey in 2007 of officials within state environmental agencies of all 50 states. Results of the survey revealed large disparities in toxicity values that were being used for TCE risk management decisions. Table II shows a summary of state TCE toxicity information that lists reference doses and slope factors for inhalation and oral routes of exposure, and appropriate references based on responses to the 2007 survey. Table III presents summary statistics for the inhalation reference dose (RfDi), the oral reference dose (RfDo), inhalation slope factor (SFi), and oral slope factor (SFo). Tables IV and V provide individual source and value rankings for the RfDi, RfDo, SFi, and SFo. In summary, results of the survey indicated that reference dose values used differed by three orders of magnitude; slope factors differed by two orders of magnitude.

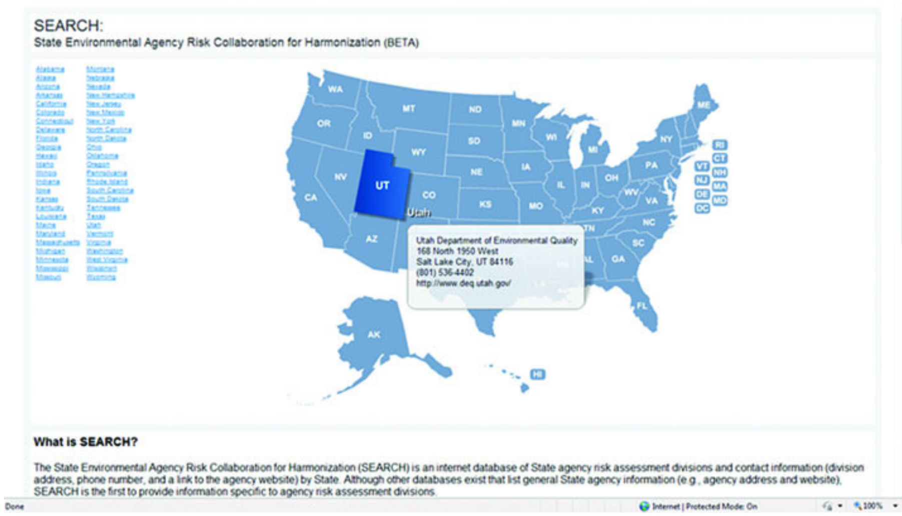

Fig. 2. Screen capture of the state environment agency risk collaboration for harmonization database.

IDEM's survey also revealed that states used a variety of sources for risk values when conducting risk assessments. Instead of using one of the risk values from the hierarchy discussed earlier, states used a variety of alternative sources of risk values, particularly in situations where federal guidance is absent, in the process of changing, or is outdated by newer science developments. In the case of TCE, some states used the risk values proposed in EPA's 2001 draft assessment, other states developed their own toxicity values, and still other states relied on older guidance documents when proceeding with site remediation and closure. Based on the 2007 survey for the TCE inhalation slope factor, 49% of states were using the 2001 draft EPA values[18]; 25% were using old IRIS-based values (including values that had been withdrawn); 18% of the states were using Cal EPA values; and approximately 6% were using state-derived values. In the case of TCE, bordering states often selected widely differing values. For example, Wisconsin selected an inhalation cancer risk value (SFi) of 0.4 mg/kg-day and Illinois selected an inhalation value of 0.006 mg/kg-day, resulting in a 67-fold difference between the neighboring states.[4]

[4]RfC and unit risk factor (URF) converted to RfDi and SFi, respectively, assuming 70 kg individual breathing 20 m^3/day of air.

Based on their interviews with other state officials, IDEM concluded that one of the main factors which influenced decisions regarding TCE risk values was the varying degrees of technical, financial, and human resources. Some states, such as Indiana and New Jersey, invested resources into the development of risk values, whereas others deferred to regional federal entities for guidance due to lack of resources. Scientific disagreements were also observed. For example, differences of opinion between the Division of Hazardous Waste Management and the Division of Emergency and Remedial Response within the Ohio EPA regarding which toxicity information to use, resulted in the use of different risk values between the two divisions.

States will need to continue to make their own decisions regarding critical risk values in the absence of EPA values for the ever-increasing number of chemicals introduced into commerce each year. To help in their efforts to do so, a collaborative approach among the states may provide a means to better channel their limited resources for maximum impact.

6. COLLABORATIVE APPROACHES

In the United States, harmonization in risk assessment across states exists through IRIS. The case

Table II. State Trichloroethylene (TCE) Toxicity Information and Sources

	State	RfDi mg/kg-day	RfDi Source	RfDo mg/kg-day	RfDo Source	Sfi $(mg/kg\text{-}day)^{-1}$	Sfi Source	SFo $(mg/kg\text{-}day)^{-1}$	SFo Source
1	Alabama	0.00567	Ext	0.006	N(O)	0.007	Cal	0.013	Cal
2	Alaska	0.01	R10	0.0003	R10	0.4	R10	0.4	R10
3	Arizona	0.011	R9	0.0003	R9	0.007	R9(Cal)	0.013	R9(Cal)
4	Arkansas	0.011	R6	0.0003	R6	0.4	R6	0.4	R6
5	California	0.17	Cal	–	–	0.007	Cal	0.013	Cal
6	Colorado	0.011	N	0.0003	N	0.4	N	0.4	N
7	Connecticut	–	–	–	–	–	–	0.089	NAS
8	Delaware	0.17	Cal	–	–	0.007	Cal	0.013	Cal
9	Florida	0.00567	Ext	0.006	N(O)	0.006	N(O)	0.011	N(O)
10	Georgia	0.01	N	0.0003	N	0.4	N	0.4	N
11	Hawaii	0.01	R9	0.0003	R9	0.4	R9	0.4	R9
12	Idaho	0.01	N	0.0003	N	0.4	N	0.4	N
13	Illinois	–	–	0.006	Cal(O)	0.006	Cal(O)	0.011	Cal(O)
14	Indiana (Comm)	0.01	R3, R9	0.0003	R3, R6, R9	0.018	IDEM	0.034	IDEM
	Indiana (Res)					0.054	IDEM	0.1	IDEM
15	Iowa	0.011	R	0.007	DWS & HA	0.385	R	0.4	R
16	Kansas	–	–	–	–	0.006	N(O)	0.011	N(O)
17	Kentucky	0.01	N	0.0003	N	0.322	KDEP	0.322	KDEP
18	Louisiana	0.014	R3	0.0003	R3	0.4	R3	0.4	R3
19	Maine	0.006	I	0.006	I	0.006	I	0.011	I
20	Maryland	0.01	R3	0.0003	R3	0.4	R3	0.4	R3
21	Massachusetts	0.05	CHEM/AAL	0.002	MADEP	0.006	E	0.011	H(W)
22	Michigan	–	–	0.0017	Dawson	0.006	EPA(87)	0.01	NCI, NTP
23	Minnesota	–	–	–	–	0.006	E	0.011	E
24	Mississippi	–	–	0.006	EPA	0.006	EPA	0.011	EPA
25	Missouri	0.17	Cal	0.17	Ext	0.007	Cal	0.013	Cal
26	Montana	0.01	N	0.0003	N	0.4	R9	0.4	R9
27	Nebraska	0.011	N	0.0003	N	0.4	N	0.4	N
28	Nevada	0.01	R9	0.0003	R9	0.4	R9	0.4	R9
29	New Hampshire	0.01	R3	0.0003	R3	0.4	R3	0.4	R3
30	New Jersey (Soil)	0.17	Cal	–	–	0.01	Cal	0.031	A-280
	New Jersey (Vapor)	0.011	R3			0.4	R3		
31	New Mexico	0.011	R6	0.0003	R6	0.4	R6	0.4	R6
32	New York	0.011	N	0.00146	HC	0.007	Cal	0.00572	NYS DEC
33	North Carolina	0.01	R9	0.0003	R9	0.4	R9	0.4	R9
34	North Dakota	–	–	–	–	–	–	–	–
35	Ohio (DHWM)	0.006	Ext	0.006	N(O)	0.006	W	0.011	W
	Ohio (DERR)	0.17	Cal	0.5	Cal(99)	0.007	Cal	0.013	Cal
36	Oklahoma	0.01	R6	0.0003	R6	0.4	R6	0.4	R6
37	Oregon	0.011	R6	0.0003	R6	0.4	R6	0.4	R6
38	Pennsylvania	0.143	A	0.006	N(O)	0.00595	N(O)	0.011	N(O)
39	Rhode Island	0.006	I	0.006	I	0.006	I	0.011	I
40	South Carolina	0.17	Cal	–	–	0.007	Cal	0.013	Cal
41	South Dakota	0.01	R3	0.0003	R3	0.4	R3	0.4	R3
42	Tennessee	0.17	Cal	–	–	0.007	Cal	0.013	Cal
43	Texas	–	–	0.006	N(O)	0.006	N(O)	0.011	N(O)
44	Utah	0.006	I	0.006	I	0.006	I	0.011	I
45	Vermont	0.01	R9	0.0003	R9	0.4	R9	0.4	R9
46	Virginia	0.01	N	0.0003	N	0.4	N	0.4	N
47	Washington	0.01	N	0.0003	N	0.4	N	0.4	N
48	West Virginia	0.01	N	0.0003	N	0.4	N	0.4	N
49	Wisconsin	0.011	N	0.007	EPA MCL	0.4	R3	–	–
50	Wyoming	0.01	R9	0.0003	R9	0.4	R9	0.4	R9

(Continued)

Table II. *(Continued)*

Notes: RfC and UR converted to RfDi and SFi, respectively, assuming 70 kg individual breathing 20 m^3/day of air. New Jersey has different RfDi and SFi for different pathways (Soil and Vapor Intrusion). Ohio has different RfDi, RfDo, SFi, and SFo for different divisions within their agency (DHWM and DERR). Indiana has different SFi and SFo for commercial and industrial settings. Wisconsin only applies RfDo to groundwater. A: ATSDR; A-280: New Jersey A-280; Cal: California EPA (Cal/EPA); Cal(99): 1999 Cal/EPA; Cal(O): Cal/EPA (Old value); CHEM/AAL: Massachusetts Chem. Health Effects Assessment Methodology/Allowable Ambient Level; Comm: commercial setting; Dawson: Dawson *et al.* (1993)[21]; DERR: Ohio Div. of Emergency & Remedial Response; DHWM: Ohio Div. of Haz. Waste Mgmt.; E: ECAO (NCEA Old Value); EPA: 1987 U.S. EPA Value; EPA MCL: U.S. EPA Maximum Contaminant Level; Ext: Extrapolated Value; DWS & HA: Drinking Water Standards & Health Advisories; HC: Health Canada; H(W): HEAST Withdrawn value; I: IRIS; IDEM: Indiana Dept. of Env. Mgmt.; KDEP: Kentucky Dept. of Env. Protection; MADEP: Massachusetts Dept. of Env. Protection; N: NCEA; NAS: National Academies of Science; NCI: National Cancer Institute; N(O): NCEA (Old Value); NTP: National Toxicity Program (1990)[11]; NYS DEC: New York State Dept. of Env. Conservation; R: Risk Assessment Info. System; R3: U.S. EPA Region III; R6: U.S. EPA Region VI; R9: U.S. EPA Region IX; R9(Cal): U.S. EPA Region IX (Cal/EPA modified); R10: U.S. EPA Region X; Res: Residential Setting; RfC: reference concentration; RfDi: inhalation reference dose; RfDo: oral reference dose; SFi: inhalation slope factor; SFo: oral slope factor; Soil: soil pathway; UR: unit risk; Vapor: vapor intrusion pathway; W: withdrawn value; –: no value specified/utilized.

Table III. Summary Statistics for RfDi, RfDo, SFi, and SFo

Statistic of Interest	RfDi mg/kg-day	RfDo mg/kg-day	SFi $(mg/kg\text{-}day)^{-1}$	SFo $(mg/kg\text{-}day)^{-1}$
No. of states with no value specified	8	9	2	2
No. of values	44	42	51	50
Mean	0.04	0.02	0.21	0.20
Median	0.011	0.0003	0.322	0.090
Most conservative value	0.00567	0.0003	0.4	0.4
No. of states using most conservative value	2	25	24	23
% of states using most conservative value	~4.6	~60	~47	46
Least conservative value	0.17	0.5	0.00595	0.00572
No. of states using least conservative value	7	1	1	1
% of states using least conservative value	~16	~2.4	~2.0	2.0
Magnitude of difference	~30	~1700	~67	~70

Notes: "Mean" and "Median" exclude states with no value specified. "% of States Using" calculated by dividing "No. of States Using" by "No. of Values". "Magnitude of Difference" = LOG10("Least Conservative" / "Most Conservative").

of TCE illustrated the large variations that can occur in risk values when states work individually. Still, we must ask if there is some scientific validity to the current approach of state-by-state assessments for chemicals not found in IRIS. In particular, when risk levels are not harmonized among states (such as the case of TCE), do differing risk levels reflect differences in risk management priorities, budgetary context, or policy decisions? Do they reflect legitimate points of scientific disagreement, or calculated cost-benefit analysis? Will harmonization, and the removal of states' individual choices, result in a lower degree of protection to the public and the environment? It is realistic to foresee that the harmonization process will inspire some scientific disagreement among state risk assessors. For example, as was discussed in the case of TCE, differences of opinion between two divisions in one state, led to the use of differing risk values in that state. Still, IDEM's survey suggested that the varying degrees of technical, financial, and human resources accounted for the observed variation in risk values. While some differences in risk management priority are understandable, it is difficult to envision a valid scientific explanation that can account for differences in risk values across the United States for one chemical by either 30-fold, 1700-fold, 67-old, or 70-fold (TCE RfDi, RfDo, SFi, or SFo values, respectively). We believe that facilitating communication among U.S. states will prompt the scientific dialogue necessary to lessen this variation. It is possible that U.S. states with more stringent regulation might face pressure to reduce their standards to enable agreement among the many, but the converse may be a more common scenario. Regardless, the consensus will be reached on a scientific basis. It also may be argued that the readiness with which states might arrive at consensus evaluations might short-circuit important

Table IV. Oral Reference Dose (RfDo) Source and Value Rankings

Rank	Aggregated Source Category Individual Sources and Ranks	No./Total	% Total	RfDo Value (mg/kg-day)	Applicable States (Aggregated)
1	New NCEA-based Sources	25/42	~60	0.0003	
	1 NCEA 2 U.S. EPA Region IX 3 U.S. EPA Region III U.S. EPA Region VI 5 U.S. EPA Region X				AK, AR, AZ, CO, GA, HI, ID, IN, KY, LA, MD, MT, NE, NV, NH, NM, NC, OK, OR, SD, VT, VA, WA, WV, WY
2	Old IRIS-based Sources	10/42	~24	0.006	
	1 NCEA (old) 2 IRIS (old) 3 Cal/EPA (old) EPA (old)				AL, FL, IL, ME, MS, OH (DHWM), PA, RI, TX, UT
3	EPA-MCL-based Sources	2/42	~4.8	0.007	IA, WI (groundwater)
	1 DWS & HA 2 EPA MCL				
4	1999 Cal/EPA	1/42	~2.4	0.5	OH (DERR)
	Dawson *et al.* 1993	1/42	~2.4	0.0017	MI
	Extrapolation from RfDi	1/42	~2.4	0.17	MO
	Health Canada	1/42	~2.4	0.00146	NY
	1992 MADEP	1/42	~2.4	0.002	MA

Notes: OH uses different numbers in their Division of Hazardous Waste Mgmt. (DHWM) and Division of Emergency and Remedial Response (DERR). WI only applies RfDo to groundwater. "RfDo Value" is the most representative value within an aggregated category. The absence of a rank indicates an equal ranking with the preceding source (e.g., U.S. EPA Region III and VI have an equal rank).

scientific deliberation in favor of expediency. A collaborative effort at the state level would be positioned to offer expediency, as the goal is to provide states with working values in a practical time frame. But the process does not need to forego quality to do so. Some states already possess state-of-the-art resources that enable them to develop their own risk values. And, like at the federal level, state-based regulatory rules-making includes a mandatory public comment period that solicits and allows further deliberation and ensures transparency.

In its purest form, a collaborative approach would act to encourage states to implement the process in unison so as to provide the equal level of protection to the public that IRIS intends to provide. Admittedly, a state-level approach to risk assessment will not likely match the scientific deliberation found in the federal process; but collaboration and harmonization among the U.S. states is not meant to replace the federal process—it is best viewed to serve as a valuable interim process that can apply as needed and as IRIS is updated to include the constantly increasing number of chemicals that are of concern to human health and the environment. As shown in the case of TCE, the current lack of dialogue among states cannot be viewed as more protective than one where U.S. states would instead proactively engage in scientific dialogue and establish consensus.

To help to predict whether collaboration among the U.S. states would benefit risk assessments, international initiatives offer examples of practical application of the structure and benefits that can result from a collaborative process. In particular, we draw on the experiences of the European Union (EU) and the International Programme on Chemical Safety (IPCS) as examples of movement to such collaborative models.

Around the world, there is call for harmonization of chemical risk assessment methods. The IPCS[24] Harmonization Project describes this as "the effort to strive for consistency among approaches and to enhance understanding of the various approaches to chemical risk worldwide," to gain "an understanding of the methods and practices used by various countries and organizations so as to develop confidence in, and acceptance of, assessments that use different approaches." Employing this concept of harmonization at the state level could help alleviate the data and

Table V. Inhalation Slope Factor (SFi) Source and Value Rankings

Rank	Aggregated Source Category Individual Sources and Ranks	No./Total	% Total	SFi Value (mg/kg-day)$^{-1}$	Applicable States (Aggregated)
1	New NCEA-based Sources	25/51	~49	0.4	
	1 NCEA 2 U.S. EPA Region III U.S. EPA Region IX 4 U.S. EPA Region VI 5 U.S. EPA Region X RAIS				AK, AR, CO, GA, HI, IA, ID, LA, MD, MT, NE, NV, NH, NJ (Vapor), NM, NC, OK, OR, SD, VT, VA, WA, WV, WI, WY
2	Old IRIS-based Sources	13/51	~25	0.006	
	1 NCEA (old) 2 IRIS (old) 3 ECAO memo EPA (old) 5 Cal/EPA (old) Withdrawn value				FL, IL, KS, MA, ME, MI, MN, MS, OH (DHWM), PA, RI, TX, UT
3	California EPA	9/51	~18	0.007	
	1 Cal/EPA 2 U.S. EPA Region IX (Cal)				AL, AZ, CA, DE, MO, OH (DERR), NY, SC, TN
4	State Sources	3/51	~5.9	Varies	IN (C), IN (R), KY
	1 IDEM 2 KDEP			0.018 (C) / 0.054 (R). 0.322	
5	California EPA NJ Soil Source	1/51	~2.0	0.01	NJ (Soil)

Notes: IN has developed different numbers for commercial (C) and residential settings (R). NJ uses different numbers for vapor intrusion and soil standards. OH uses different numbers in their Division of Hazardous Waste Mgmt. (DHWM) and Division of Emergency and Remedial Response (DERR). "SFi Value" is the most representative value within an aggregated category. The absence of a rank indicates an equal ranking with the preceding source (e.g., U.S. EPA Region III and IX have an equal rank).

safety gaps in U.S. chemical regulation and streamline the risk assessment process.

In 2006, the EU adopted new legislation addressing the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH). In essence, the Directive assigned a greater responsibility to industry to manage the risks from chemicals and to affirmatively and publicly provide safety information on each substance. The Directive also called for the progressive substitution of chemicals proven to be harmful when suitable alternatives have been identified.[25]

Prior to adopting REACH, however, the EU had established and relied on a collaborative process to complete risk assessments. In the mid 1990s, the Council of the European Communities enacted Council Regulation (EEC) No. 793/93 and its companion regulation No. 1488/94.[26,27] Together, these regulations provided a framework for risk evaluation and control of existing substances consisting of four stages: (1) data collection, (2) priority setting, (3) risk assessment, and (4) risk reduction. The later regulation expanded on the risk assessment component; it presented Member States with the responsibility of completing risk assessments for existing substances and outlined the required components for each risk assessment report. But perhaps most relevant to the situation facing the U.S. states, each regulation contained a stipulation that Member States complete risk assessments at a "Community level," based on the premise that a Community-level risk assessment can "avoid disparities between Member States which would not only affect the functioning of the internal market but would also fail to guarantee the same level of protection of man and the environment."[27]

These regulations and the accompanying Technical Guidance Document established the basic framework for the preparation of a collaborative, harmonized Risk Assessment Report (RAR).[28] In summary, a Member State volunteered to act as "Rapporteur" for a substance on the priority list (the priority list is drawn up by the Commission in consultation with Member States). The Rapporteur, in conjunction with industry stakeholders, prepared a detailed draft risk assessment for the chosen substance typically within 12 months from priority list publication. Upon completion, the Rapporteur presented the draft RAR to technical experts representing other Member States for endorsement. The Scientific Committee on Toxicity, Ecotoxicity, and the Environment (CSTEE) would next conduct a peer review and give its opinion to the European Commission regarding the quality of the RAR and its conclusions.[29] The Commission then prepared a final proposal for discussion; adoption was by simple majority vote of the Committee, composed of representatives from all Member States and chaired by a representative of the Commission. Once approved, summaries of adopted RAR's were published in the Official Journal.

The theoretical framework of the EU Directives' risk assessment process was well-intentioned. Although rigorous examination is beyond the scope of this article, we offer results from two studies that evaluated the process. Munn and Hansen conducted a preliminary analysis of the risk assessment process, and focused on if and how policy influenced regulatory decisions.[29] They argued that any risk assessment process can easily be defeated by disagreements resulting from the gap between science and policy, which tends to occur when there is insufficient evidence to declare that risk posed by any substance is "acceptable" or "not acceptable." The analysis was conducted on 22 risk assessments, six of which had undergone the entire process under Regulation 793/93, and 16 that had been reviewed by the CSTEE, but had not yet undergone the full process.[26] Munn and Hansen found that the CSTEE agreed with the majority of the conclusions of RARs submitted for review, with a few exceptions due to policy-based decisions (e.g., the precautionary principle, exposure minimization for carcinogens, avoid unnecessary animal testing), and very few disagreements resulted from differing scientific opinions.[29] Thus, even though the science–policy gap slowed down the process for a few chemicals, the authors found that the process was smooth for the majority of substances. Further, their analysis concluded that the RAR process "provide(d) a transparent account of the scientific basis for regulatory decisions made under the Regulation."[29]

Bodar *et al*. evaluated the first group of risk assessments (41) from the priority list and found that even though the performance of the process had been criticized by policy makers and nongovernmental organizations as being slow and ineffective, Member States had been able to complete a significant number of high-quality RARs, particularly for "difficult" (i.e., of wide use or having controversial toxicity data) substances.[30] For example, the United Kingdom finalized their TCE RAR in 2004 following review and endorsement by technical experts from Member States and the CSTEE.[31] These accomplishments by the EU have demonstrated that a collaborative process toward risk assessment can be an effective way of completing a sensible number of risk assessments without foregoing quality across a wide and populous geographic area.

The EU's pre-REACH risk assessment process provides us with a working example of a systematic interagency collaborative risk assessment process. The collaboration among Member States seen in the EU could serve as a model for formal cooperation between U.S. states. The adoption and adaptation of such a model could be of particular use for those substances that are commonly found in contaminated sites but do not have final IRIS assessments. Organized cooperation has the potential to increase the level of scientific exchange and bring substantive discussions among state assessors and can help to reduce the duplication of effort that can occur when states conduct assessments independently and unaware of other's work. The goal of the collaborative effort is for states to agree on a harmonized approach that will allow state officials to make risk management decisions that offer scientifically sound and consistent protection for residents of every state in the absence of guidance from U.S. EPA. Considering the backlog of chemicals in need of health assessment, it appears that a collaborative approach among states forms a feasible, affordable strategy that could help streamline and harmonize chemical risk assessment in the United States.

7. A TOOL TO FOSTER COLLABORATION IN THE UNITED STATES: SEARCH

As the ultimate authority on most site cleanup and emissions-permitting decisions, each U.S. state makes its own risk management decisions. However, these decisions can affect interstate relations, and

Table VI. Organizations Facilitating Interagency Collaborations in the United States

Alliance for Risk Assessment (ARA)—The ARA is a collaboration of organizations that fosters the development of technical chemical risk assessment products and services, through a team effort of specialists and organizations dedicated to protecting public health by improving the process and efficiency of risk assessment, and to increasing the capacity for developing risk values to meet growing demand. www.allianceforrisk.org
Association for Environmental Health and Sciences (AEHS)—AEHS exists to facilitate communication and collaboration among environmental health and science professionals in the areas of soil and water contamination. AEHS provides technical support, peer review, and expert witnesses for litigation purposes. www.aehs.com/
Environmental Council of the States (ECOS)—ECOS is a nonprofit association of U.S. state and territorial environmental agency leaders whose purpose is to improve state agency capabilities that will lead to better protection of public health and the environment. www.ecos.org/
Federal–State Toxicology Risk Assessment Committee—with representatives from state health and environmental agencies and EPA Headquarters and Regional personnel, fosters cooperation, consistency, and an understanding of EPA's and different States' goals and problems in human health risk assessment. http://water.epa.gov/aboutow/waterscience/fac/fstrac/index.cfm
Interstate Technology and Regulatory Council (ITRC)—The ITRC develops information resources and help break down barriers to the acceptance and use of technically sound innovative solutions to environmental challenges through an active network of diverse professionals. ITRC consists of 50 states, the District of Columbia, multiple federal partners, industry participants, and other stakeholders, cooperating to break down barriers and reduce compliance costs, making it easier to use new technologies, and helping states maximize resources. www.itrcweb.org/
Multistate Working Group (MSWG)—MSWG is a multistakeholder network that works to improve environmental performance, economic sustainability, social responsibility, and quality of life. www.mswg.org/
Northeast States for Coordinated Air Use Management (NESCAUM)—NESCAUM is a nonprofit association of air quality agencies in the Northeast, that provides scientific, technical, analytical, and policy support to the air quality and climate programs of the eight Northeast states. www.nescaum.org/
Northeast Waste Management Officials' Association (NEWMOA)—NEWMOA is an interstate association where northeastern states collaborate to identify new solutions to environmental issues related to hazardous waste, solid waste, waste-site cleanup, and pollution prevention. www.newmoa.org/

can become problematic if neighboring states select wildly different pollution standards. In effort to keep up with the daunting workload, states sometimes form partnerships with other states or join nonprofit organizations to share technical risk assessment expertise. The formation of these interstate groups helps states pool resources and move toward consensus on complex risk issues. Table VI provides a nonexhaustive list of some organizations working to facilitate interagency collaborations.

Recognizing the limitations of current practices, several groups have suggested strategic improvements to U.S. state regulatory practices. For example, the Lowell Center for Sustainable Production, University of Massachusetts Lowell, published "*Options for State Chemicals Policy Reform: A Resource Guide*".[32] This document explored policy options and structures that states can implement to reform the current federal chemicals management policy and regulations. Recently, EPA has also begun encouraging collaboration to promote consistency and efficiency. In a 2007 Office of Enforcement and Compliance Assurance release "*Guide for Addressing Environmental Problems: Using an Integrated Strategic Approach*," EPA introduced a strategic approach to solving environmental problems in a more efficient and effective manner, promoting consistency in planning and implementation, transfer of knowledge through the sharing of lessons learned, and establishing a framework to guide planning and decision making. EPA claimed the following benefits to such an approach:

- increased communications across different offices possibly resulting in new ideas for solving environmental problems;
- less time spent duplicating efforts;
- enhanced efficiency and effectiveness of human and financial resources; and
- more measurable results.[33]

While the EPA document was directed at addressing compliance issues, the same principles and benefits of this collaborative approach can be applied to risk assessment across U.S. state environmental agencies.

7.1. Introducing SEARCH

The available evidence suggests that collaborative approaches will promote greater efficiencies in risk value development. Therefore, we created the SEARCH (see Fig. 2). SEARCH is an internet database that identifies state agency risk assessment divisions and contact information (division address, phone number, and a link to the agency website) by State. It was developed to serve as a platform for sharing of risk assessment information, with the belief that a first and critical step toward collaboration is increasing communication among U.S. state agencies.

7.2. Survey of State Risk Assessors

Prior to designing SEARCH, we contacted state agency risk assessors from all 50 U.S. states, initially via electronic mail and subsequently (if necessary) by telephone to ensure the completion of our database. State agencies were asked to identify the division/department responsible for human health risk assessments and to provide contact information. In addition, agencies were asked for suggestions on the type of risk assessment information they would find most useful. We felt it was important to involve the agencies in the creation of SEARCH, as this tool is intended for their use. Results and suggestions from all of the agencies were collected and evaluated for inclusion in SEARCH.

7.3. Results

Forty-one of 50 states responded to our inquiries. The results of the survey indicate that there was no user-friendly online tool available that states can use to supplement the work of existing interstate membership organizations and committees. Our interviews with state risk assessors indicated that an overwhelming majority of the states would like to have a resource to provide timely information on how other states approach risk assessments in the absence of federal guidelines. When asked if they were aware of any existing database that could provide such risk information for each state, the majority of states indicated they were not aware of such a resource. Twenty-one respondents indicated that they would like SEARCH to include a list of risk values by state, and assumptions supporting those values, particularly for those substances not included in IRIS. Other suggestions from states included a regularly updated list of significant risk assessment-related actions and risk policy decisions, by state, as well as links to state-approved risk assessment guidance documents.

7.4. Understanding SEARCH

To our knowledge, SEARCH is the only internet database that identifies U.S. state agency risk assessment divisions and contact information (division address, phone number, and a link to the agency website) by state. Although other databases exist that list general state agency information (e.g., address and website), SEARCH is the first to provide information specific to agency risk assessment divisions. Because state agency risk assessment capabilities vary widely, contact information for state agency risk assessors is not always easily obtained or available on state agency websites, particularly if a state agency delegates that responsibility to another agency (e.g., state health department). Most agency websites offer a staff contact list, but no information on the staff members' department or position, making it difficult and time-consuming to identify the proper contact. SEARCH will ensure that state risk assessors can access this information quickly by providing a direct contact to the division or department responsible for risk assessments within each state, thereby facilitating communications among state risk assessors and encouraging states to share risk information.

SEARCH is freely available at www.allianceforrisk.org/SEARCH/index.html. Upon entering the SEARCH homepage, users are presented with an interactive U.S. map. Once a user clicks on the desired state, SEARCH directs the user to a new page containing the name of the agency division or other agency department responsible for human health risk assessments, address, and phone number.

In addition, SEARCH will enable state risk assessors to track the latest developments in the risk assessment field. The home page will contain links to the most up-to-date risk-related information interfacing with the Risk Information Exchange (RiskIE), the Alliance for Risk Assessment's database of in progress chemical risk assessment work, training modules, white papers, and other risk-related documents.[34] In essence, SEARCH is a platform for collaboration to encourage more efficient and effective risk management, especially for states confronted with dwindling technical, financial, and human resources.

Finally, in an effort to maintain continuous communications with states regarding content, SEARCH will include a "State Feedback" item on the home page. The "State Feedback" will allow states to provide further suggestions for improvement of SEARCH. This key feature will ensure that

SEARCH effectively promotes harmonization and collaboration enabling states to not only participate but even to lead.

7.5. Strengths and Limitations

Because SEARCH is an evolving tool intended for U.S. state agency use, its success will depend largely on state risk assessors' involvement. The majority of states that responded were enthusiastic about the creation of SEARCH, stressing the need and value of this tool given their shrinking budgets. In their responses, several states even provided links to state-specific risk-related information they felt would be useful to other states. Despite the initial enthusiasm, we acknowledge that some state risk assessors may not use SEARCH. Nine states did not respond to our queries despite several attempts to contact them. In addition, two of the risk assessors contacted questioned the need for a state risk assessment contact or risk information database because the information they use regularly is available on IRIS or other federal sources. While it is good to hear their data needs are currently being met, we hope to engage these agencies in the event that future contaminants are without federal values. Currently, SEARCH includes contacts for state agencies, but does not include risk values. In the future, SEARCH is intended to interface with existing platforms, such as the International Toxicity Estimates for Risk (ITER), which houses peer-reviewed risk values from organizations around the world (www.tera.org/iter/).

One limitation of the database is the ever-changing content. Maintaining accurate records of State information will be critical to the utility of SEARCH. The upkeep of the database will be managed by the Alliance for Risk Assessment (ARA), and paid for by the ARA Impact Fund. Current information will be maintained through annual contact directly with the State agencies, and through voluntary updates provided by individual States.

8. CONCLUSION

U.S. states risk assessment agencies are faced with dwindling resources, but environmental and public health protection is as important as ever. The TCE example demonstrates that without federal standards, U.S. states must work independently to derive their own toxicity values or consult other risk value resources through informal contacts. The resulting wide range of toxicity values across the United States creates questions about the scientific credibility and the quality of the public health protection provided. We believe harmonization and collaboration among U.S. states can result in a cohesive, credible approach that ensures public health protection. Groups such as the IPCS and the EU and its Directives more than a decade ago proved that a collaborative approach to risk assessment can work and the emphasis on harmonized approaches in toxicology and risk assessment continues. Drawing upon the EU's experiences, TERA developed SEARCH for U.S. state and community-based risk assessors. SEARCH is intended to meet the needs of U.S. state risk assessors faced with limited resources to identify and implement new strategies to cope with the volume of chemicals entering commerce each year across the country, and continue to protect the public and the environment.

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